# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



| Applicant's or agent's file reference | **FOR FURTHER ACTION** | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
|---|---|---|
| 100505 | | |
| International Application No. | International Filing Date *(day/month/year)* | Priority Date *(day/month/year)* |
| **PCT/AU00/00671** | 16 June 2000 | 18 June 1999 |

International Patent Classification (IPC) or national classification and IPC

**Int. Cl.** [7] A61K 39/395, 38/17 A61P 35/00, 35/04

Applicant

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1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

| | | |
|---|---|---|
| I | ☒ | Basis of the report |
| II | ☐ | Priority |
| III | ☐ | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | ☐ | Lack of unity of invention |
| V | ☒ | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | ☐ | Certain documents cited |
| VII | ☐ | Certain defects in the international application |
| VIII | ☐ | Certain observations on the international application |

| Date of submission of the demand | Date of completion of the report |
|---|---|
| 17 January 2001 | 9 October 2001 |
| Name and mailing address of the IPEA/AU | Authorized Officer |
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
**PCT/AU00/00671**

**I. Basis of the report**

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|---|---|---|
| Novelty (N) | Claims **6-8, 13-15, 20, 24-26** | **YES** |
| | Claims **1-5, 9-12, 16-19, 21-23** | **NO** |
| Inventive step (IS) | Claims - | **YES** |
| | Claims **1-26** | **NO** |
| Industrial applicability (IA) | Claims **1-26** | **YES** |
| | Claims - | **NO** |

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1) US 5578482 A

D2) US 5820859 A

D3) WO 91/02062 A

D4) WO 98/35036 A

D5) WO 91/08214 A

D6) WO 98/30704 A

D7) SLIWKOWSKI, M et al;

D8) KLAPPER, L et al. Oncogene,

D9) KLAPPER, L et al. Proc. Nat. Acad. Sci. USA.,

D10) VIJAPURKAR, U et al

D11) PARK, B et al

D12) RAM, T et al

D13) PINKAS-KRAMARSKI, R et al

Novelty (N) Claims 1-5, 9-12, 16-19, 21-23

Each of D1-10 disclose the role of ErbB-2 and ErbB-3 in the role of cancers and tumours including those presently claimed and exemplified. These roles are discussed individually for each receptor or as heterodimers. The use of mutants (D7, D10), ligands (D1, D3) and antibodies (such as L26, L96, N12 -D2, D5, D8, D9), heregulin variants (D4) and CHK (D6) in the blocking of these receptors are also disclosed. Thus claims 21-23 are disclosed.

Documents D1-D6 disclose the methods of claims 1-5, 9-12 and 16-19 and, as such, these claimsdo not fulfil the requirements for novelty (Article 33(3)).

Inventive Step (IS) Claims 1-26

Claims 1-5, 9-12, 16-19, 21-23 as above.

Each of D1-13 disclose the role of ErbB-2 and ErbB-3 in the role of cancers and tumours including those presently claimed and exemplified. These roles are discussed individually for each receptor or in a heterodimer. The use of mutants, ligands and antibodies, heregulin variants and CHK in the blocking of these receptors is also disclosed.

Thus claims 1-26 do not fulfil the requirements for inventive step (Article 33(3).

(Continued in Supplemental Box)

**Supplemental Box**
(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Box 1**

Rule 67 lists the subject matter which under Article 34(4)(a)(i) an international preliminary examination is not required to be carried out. At item (iv) it specifies methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods, as such matter. However the agreement between WIPO and Australia further qualifies this by excepting from exclusion any subject matter which is examined under national grant procedures. Claims 1-16 have nonetheless been considered because the identified subject matter does not contravene Australian law.

**Supplemental Box**
(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Box V**

The receptors are known to comprise an extracellular domain which would be used to form the described heterodimer. Therefore the choice of an antibody or ligand to either or both of the extracellular domains to perform the present invention as claimed in claims 6-8, 13-15 and 20 is considered non-inventive, particularly when the antibodies are known. The composition claims 24-26 comprising known compounds known to be effective in the claimed treatments lack inventiveness.

In light of documents D1-13 alone or in combination, the Person Skilled in the Art with the same problem to be solved as the Applicant would be led to investigate the binding characteristics of either one or both of the described receptors using well known techniques such as the use of ligands and antibodies in the treatment of cancers and/or tumours. This investigation would involve the use of antibodies known to bind to the described receptors thereby inherently preventing the formation of the described ErbB-2/ErbB-3 heterodimer formation. Thus claims 1-26 lack inventiveness.

Industrial Applicability Claims 1-26

Claims 1-26 are considered to be industrial applicable.